TITLE: **Informed Consent**			DOCUMENT NUMBER: **IRB-010**
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IRB CHAIR OR DESIGNEE:	ACOS R&D:	COMPLIANCE:
Signature	Signature	Signature
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Date: 3/26/04	Date: 3-31-04	Date: 4/8/04

1 POLICY

It is Stratton VA Medical Center's policy to comply with all applicable local, state, federal, and international GCP regulations in the conduct of clinical research studies. Written procedures are required to guide the IRB in the review of research.

The IRB recommends that all consent documents follow the Stratton VA IRB Template Consent to ensure that all required and appropriate additional elements of consent are present in the consent document. Exceptions are allowed on a case-by-case basis. The consent should be written at an 8th grade reading level.

Whenever the IRB requires documentation of informed consent, and before a subject can participate in the research, the consent document must be signed and personally dated by the subject or by the subject's legally authorized representative, and by the person who conducted the informed consent discussion. Before participation in the trial, the subject or the subject's legally authorized representative must be given a copy of the signed and dated written informed consent form and any other written information provided to the subjects. During a subject's participation in the trial, the subject or the subject's legally authorized representative must be given a copy of the signed and dated consent form updates and a copy of any amendments to the written information originally provided.

If a subject is unable to read or if a legally authorized representative is unable to read, an impartial witness must be present during the entire informed consent discussion. After the written informed consent and any other written information to be provided to subjects is read and explained to the subject or the subject's legally authorized representative, and after the subject or the subject's legally authorized representative has orally consented to the subject's participation in the trial and, if capable of doing so, has signed and personally dated the informed consent form, the witness must sign and personally date the consent form. By signing the consent form, the witness attests to being present and observing the subject's signature.

2 FORMS

Stratton VA Template Consent

3 PROCEDURE

3.1 Unless waived or exempted by the IRB, the IRB may not approve a research protocol involving human subjects unless:

3.1.1 The investigator obtains the legally effective informed consent of the subject or the subject's legally authorized representative.

3.1.1.1 If someone other than the investigator conducts the interview and obtains consent from a subject, the investigator has to formally delegate this responsibility to a person who has received the appropriate training to perform this activity.

3.1.2 The investigator seeks such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate, and that minimize the possibility of coercion or undue influence.

3.1.3 The information given to the subject or the representative is in language understandable to the subject or the representative and the impartial witness, where applicable.

3.1.4 The informed consent, whether oral or written, does not include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

3.1.5 The Stratton VA Template Consent, VA Form 10-1086, must be used as the consent form, and all required elements must be completed.

3.2 **Basic elements of Informed Consent:** Unless exempted, waived, or altered by the IRB, the IRB may not approve a research protocol involving human subjects unless in seeking informed consent the following information will be provided to each subject:

3.2.1 The name of the study and the name of the Principal Investigator conducting the study.

3.2.2 A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

3.2.3 A description of any reasonably foreseeable risks or discomforts to the subject.

3.2.4 A description of any benefits to the subject or to others that may reasonably be expected from the research.

3.2.5 Disclosures of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.

3.2.6 A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

3.2.7 A statement that the Food and Drug Administration (FDA), the Office of Human Research Protections (OHRP), the National Institutes of Health (NIH), and the VA Office of Research Oversight (ORO) may have access to the records.

3.2.8 For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

3.2.9 An explanation of whom to contact for answers to pertinent questions about the research and research subjects rights, and whom to contact in the event of a research-related injury to the subject.

3.2.10 A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

3.2.11 A statement that if the participant takes part in the study, the participant may still have to pay the usual VA charges.

3.3 **Additional Elements of Informed Consent**: When appropriate, one or more of the following elements of information will also be provided to each subject:

3.3.1 A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable.

3.3.2 Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

3.3.3 Any additional costs to the subject that may result from participation in the research, consistent with the Federal laws concerning veteran's eligibility for medical care and treatment.

3.3.4 The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

3.3.5 A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

3.3.6 The approximate number of subjects involved in the study.

3.3.7 A statement that the human biologic specimens obtained could be part of, or lead to the development of a commercially valuable product, if applicable.

3.3.8 A statement that indicates if the specimens are to be retained after the end of the study.

3.3.9 The probability for random assignment to each treatment.

3.3.10 The subject's responsibilities.

3.3.11 Information regarding payment to subjects, including the methods, amounts, schedule of payment to trial subjects, and the way payment will be prorated.

3.3.12 A statement that the monitor(s), the auditor(s), the IRB, and the regulatory authority (ies) will be granted direct access to the subject's original medical records, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally authorized representative is authorizing such access.

3.3.13 A statement that records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the research are published, the subject's identity will remain confidential.

3.4 The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

3.4.1 The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

3.4.1.1 Public benefit or service programs;

3.4.1.2 Procedures for obtaining benefits or services under those programs;

3.4.1.3 Possible changes in or alternatives to those programs or procedures; or

3.4.1.4 Possible changes in methods or levels of payment for benefits or services under those programs; and

3.4.2 The research could not practicably be carried out without the waiver or alteration.

3.5 The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

3.5.1 The research involves no more than minimal risk to the subjects.

3.5.2 The waiver or alteration will not adversely affect the rights (including privacy rights) and welfare of the subjects.

3.5.3 The research could not practicably be carried out without the waiver or alteration.

3.5.4 Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

3.6 The IRB may require that information, in addition to that specifically mentioned above, be given to the subjects when in the IRB's judgment the information would add to the protection of the rights and welfare of subjects.

3.7 The informed consent requirements in this SOP are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

3.8 The IRB will not review or approve research that requests a waiver of the requirements for informed consent per 21 CFR 50.24 "Exception from informed consent requirements for emergency research."

3.9 Documentation of Informed Consent

3.9.1 Informed consent must be documented by the use of a written form approved by the IRB, and signed and dated by:

3.9.1.1 The subject or the subject's legally authorized representative,

3.9.1.2 A witness whose role is to witness the subject's or the subject's legally authorized representative's signature, and

3.9.1.3 The person obtaining the informed consent.

3.9.2 VA Form 10-1086 must be used as the consent form.

3.9.2.1 A note must be placed under the witness' signature line if the sponsor or the IRB requires a witness to the consent process in addition to the witness to the subject's signature or

3.9.2.2 If the same person needs to serve both capacities.

3.9.2.3 The consent form must be the most recent IRB approved consent form and must include the stamped approval and expiration dates on each page.

3.9.2.3.1 The IRB must maintain a copy of each approved consent form in its records.

3.9.2.4 The original signed consent form must be filed in the subject's case history.

3.9.2.5 A copy of the signed informed consent must be provided to the subject or the subject's legally authorized representative.

3.9.3 The subject's involvement in research must be documented in the individual's electronic medical record to protect the subject's safety.

3.9.3.1 The required information in the medical record includes:

3.9.3.1.1 The title of the research study.

3.9.3.1.2 The name of the Principal Investigator and other relevant study personnel.

3.9.3.1.3 The name of the individual who obtains the informed consent.

3.9.3.1.4 Contact information in case of emergency or need for further information regarding the study or therapy.

3.9.3.1.5 A statement that the study was explained to the subject.

3.9.3.1.6 A statement that the subject was given the opportunity to ask questions.

3.9.3.1.7 Study inclusion and exclusion criteria and documentation that the subject met all of the criteria.

3.9.3.1.8 A note indicating when the subject actually entered into the study and when the subject's participation in the study is terminated.

3.9.3.1.9 All other information appropriate to the study.

3.9.3.2 The IRB does not flag the medical record if:

3.9.3.2.1 The subject's participation in the study involves only one encounter, only the use of a questionnaire, or the use of previously collected biological specimens.

3.9.3.2.2 The identification of the patient as a subject in a particular study would place the subject at greater than minimal risk.

3.9.4 A short form of the written consent document stating the elements of informed consent and presented orally to the subject or the subject's legally authorized representative may be used if:

3.9.4.1 The IRB approves the written summary of what is to be said to the subject or the subject's legally authorized representative.

3.9.4.2 Only the short form is to be signed by the subject or the subject's legally authorized representative.

3.9.4.3 The witness must sign both the short form and a copy of the summary, and the person actually obtaining the consent must sign a copy of the summary.

3.9.4.4 The original short form and summary must be filed in the subject's case history.

3.9.4.5 A copy of the summary must be given to the subject or the subject's legally authorized representative, in addition to a copy of the signed short form.

3.10 Waiver of Requirement for a Signed Informed Consent

3.10.1 The IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects, if it finds either:

3.10.1.1 That the only record linking the subject and the research is the consent and the principal risk to the subject would be potential harm resulting from a breach of confidentiality.

3.10.1.1.1 Each subject must be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

3.10.1.2 That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

3.10.2 When the documentation requirement is waived, the IRB must document the reason for the waiver and may require the investigator to provide subjects with a written statement regarding the research.

3.11 An addendum consent may be required if:

3.11.1 The investigator or the IRB determines that additional information regarding the study should be distributed to subjects.

3.11.1.1 The addendum consent format should include the basic elements of consent as in 3.2.

3.11.1.2 The investigator may revise the original approved consent form, in lieu of an addendum consent, to be reviewed and approved by the IRB.

3.12 Informed consent copies are to be sent to the Research Office within 5 days of obtaining signature, and to HIMS for scanning into EMR.

3.13 The IRB does not permit the use of a group consent process.